

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte Thomas R. Barnett, James J. Elting,
Michael E. Kamarck, and Axel W. Kretschmer

Appeal No. 1996-1090
Application No. 08/027,974

Heard: March 9, 2000

Before WINTERS, ROBINSON, and LORIN, Administrative Patent
Judges.

LORIN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. ' 134 from the final rejection of claim 19. On consideration of the record, we reverse the Examiner's decision rejecting this claim.

The sole claim on appeal is
19. A peptide having an amino acid sequence
corresponding to the entire amino acid sequence or a
fragment thereof of the expression product of a cell
that is transfected, infected or injected with a
recombinant cloning vehicle, said fragment

exhibiting immunological cross-reactivity with a CEA family member and having no less than five amino acids, and said recombinant cloning vehicle coding for a CEA family polypeptide selected from the group consisting of sequences TM-2, TM-3 KGCEA1 and KGCEA2, or a synthetic peptide corresponding to said expression product, or a labeled form thereof.

The sole rejection is:

Claim 19 is rejected under 35 U.S.C. ? 112, first paragraph, for failing to provide an enabling disclosure.

Decision

Examiner has rejected claim 19 for failing to comply with the enablement requirement of 35 U.S.C. ? 112, first paragraph:

The specification shall contain a written description of ... the manner and process of making and using [the claimed invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which [the invention] pertains, or with which it is most nearly connected, to make and use [that invention].

The issue for our determination is significantly narrowed as a result of concessions made by the Examiner. According to the examiner:

The entire peptide is enabled.² Consequently, the enablement issue surrounding claim 19, which is

² "Examiner respectfully reminds the board that the Examiner has indicated that the entire length peptides have been indicated as allowable. The novelty [, sic] obviousness and enablement of those proteins is [are, sic] not an issues [issue, sic] instantly. The sole issue remaining is the enablement of the peptide fragments of those proteins." Examiner's Answer, p. 2.

directed to both the entire peptide and a fragment thereof, involves the claimed fragment only.

One with skill in the art can "make" the claimed invention without undue experimentation.³

Consequently, the focus of attention is on how to "use" the claimed invention only.

Accordingly, the issue is whether the specification enables a person skilled in the art to use the claimed fragment.

There are two uses disclosed in the specification. First, on page 24 and in the claim, Appellants describe immunological cross-reactivity with a CEA family polypeptide. There is no dispute that "Appellants have disclosed the full-length sequences and also taught those skilled in the art that fragments exhibiting immunological cross-reactivity with a CEA family member will be useful." Brief, p. 12. Second, on page 3, Appellants describe immunoassays which can distinguish between CEA and CEA-like antigens.

Regarding the first use, appellants assert that "the determination of which fragments exhibit cross-reactivity

³ "Declarant states that with regard to (1), ?obtaining the polypeptide fragments does not present undue obstacle and is within the skill of the ordinary practitioner in the art.? The Examiner agrees with this statement since this aspect was not the basis for the rejection." Advisory Action, p. 2.

with a CEA family member involves routine techniques."⁴
This is supported by a declaration (paper no. 18, p. 5)
which states that "confirming a given fragment exhibits
immunological cross-reactivity with a CEA family member
also does not present any undue obstacle and is within
the skill of the ordinary practitioner in the art."
Examiner does not appear to challenge these statements
and in fact concedes that antibodies can be made from the
claimed fragment,⁵ a necessary step to achieving a cross-
reactivity with a CEA family member. If antibodies can
be made from the claimed fragment and no undue
experimentation is required to react the antibodies with
CEA molecules, it follows therefore that the
specification fully enables one to use the claimed
fragment I in obtaining antibodies for reactivity with
CEA molecules.

Examiner takes the position⁶ that while one might be

⁴ "The examiner concedes that obtaining the fragments is not a basis for this rejection. The Examiner also apparently concedes that the determination of which fragments exhibit cross-reactivity with a CEA family member involves routine techniques." Brief, p. 12.

⁵ "Appellants' distortion of the enablement rejection does not make since [sense, sic] as Examiner has repeatedly conceded that one can make peptides and raise antibodies to them." Examiner's Answer, p. 4.

⁶ "Appellant's arguments are deceptive in that [they, sic] argue against rejections that are not of record. In paper 14 [Advisory Action] page 3, lines 5-7 the Examiner

enabled to use the claimed fragment to make antibodies reactive to CEA, one would not be enabled to use the fragments to make antibodies which can more specifically differentiate between CEAs and CEA-like peptides.

Examiner argues that more is required than mere antigenicity⁷ - that Appellants must show that one would be enabled to use the claimed fragment to make antibodies which can more specifically differentiate between CEAs and CEA-like peptides. We disagree.

First, absent evidence to the contrary, using the claimed fragment to make antibodies reactive to CEA is a specific, credible, and substantial utility on which Appellants can rely for enablement. "The PTO must have adequate support for its challenge to the credibility of

states that the lack of enablement resides in the production of CEA **specific** [Examiner's emphasis] antibodies to detect CEAs- that is to differentiate CEAs from CEA-like peptides, not that Examiner questions the ability of the CEA to be immunogenic (Appellants seem to be arguing that if the peptides are immunogenic- that is antibodies can be raised to them- then they are enabled, which is simply inconsistent with the stated utility for the peptides)." Examiner's Answer, pp. 3-4.

⁷ In the Examiner's Answer (p. 5), certain passages are reproduced from the specification in order to show that an ability to cross-react with a CEA family member does not provide one an ability to measure tumor-specific CEA levels. According to the Examiner

These passages clearly bolster Examiner's position that antigenicity is insufficient for enablement and contradict Appellants contention that antigenicity [antigenicity, sic] is sufficient for enablement. Examiner's Answer, p. 5.

applicant's statements as to utility. Only then does the burden shift to appellant to provide rebuttal evidence. In re Gardner, 475 F.2d 1389, 1391, 177 USPQ 396, 397 (CCPA 1973); In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971)" In re Bundy, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981). Here, Examiner makes no comment as to the specific, credible, and substantial nature of this use and therefore the burden does not shift to appellants to prove another use for the claimed fragment.

Second, given that one would be enabled to use the claimed fragment for purposes of cross-reactivity with CEA molecules, it is unnecessary to also determine whether the specification would enable one of skill to use the claimed fragment for differentiating between CEAs and CEA-like peptides. "A claimed invention need not accomplish all objectives stated in the specification," Raytheon Company v. Roper Corporation, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984).⁸

⁸ "3. A claimed invention need not accomplish all objectives stated in the specification. The district court held the '520 patent invalid in part because Roper's oven, as set forth in claims interpreted by the district court as requiring prevention of backflow and autoignition, failed to accomplish all objectives stated in the patent. Raytheon urged at oral argument that that holding is compelled by Mitchell v. Tilghman, 86 U.S. 287, 396-97 (1873) (a patent is void "if the described result cannot be obtained by the described means"). In

In other words, even if, for argument's sake, the Examiner is correct, one would nonetheless be enabled to use the claimed fragment to make antibodies reactive to CEA. As we stated, this objective is disclosed and one would be enabled to accomplish that objective. That is all that is necessary. Given that the claim is specifically limited to that use and not drawn to the differentiation of CEAs and CEA-like peptides, the "use" prong of the first paragraph of 35 U.S.C. ? 112 is satisfied.

Accordingly the rejection of claim 19 for lack of enablement under 35 U.S.C. ? 112 is reversed.

REVERSED

Mitchell, the described result was production of fatty acids and glycerin from fatty or oily substances by the action of water at high temperature and pressure. Id. at 296, 380. That was the single result stated and was an element of the claim. Id. at 296. To interpret Mitchell as requiring that all claims must set forth inventions satisfying all objectives would make no sense. When a properly claimed invention meets at least one stated objective, utility under ? 101 is clearly shown. See e.g., Standard Oil Co. (Indiana) v. Montedison, S.P.A., 664 F.2d 356, 375, 212 USPQ 327, 344 (3rd Cir. 1981), cert. denied, 456 U.S. 915 (1982); E.I. du Pont de Nemours & Co. v. Berkley & Co., 620 F.2d 1247, 1258 n.10, 1260 n.17, 205 USPQ 1, 8 n.10, 10 n.17 (8th Cir. 1980); Krantz and Croix v. Olin, 148 USPQ 659, 661-62 (CCPA 1966); Chisum on Patents, ?4.04.?

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